In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1364V UNPUBLISHED

SAEEDA SYED,

Petitioner.

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 28, 2021

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

David Charles Richards, Christensen & Jensen, P.C., Salt Lake City, UT, for Petitioner.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On September 6, 2019, Saeeda Syed filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA"), as defined in the Vaccine Table, after receiving the influenza ("flu") vaccine in her right deltoid on September 9, 2017. Petition at 1, ¶¶ 3, 41. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find the flu vaccine was administered in Petitioner's right deltoid as alleged.

I. Relevant Procedural History

Along with the Petition, Ms. Syed filed the majority of the medical records required under the Vaccine Act. Exhibits 1-19, ECF No. 1; see Section 11 (c). She filed the remaining records ten days later. Exhibits 20-21, ECF No. 6. On November 17, 2019, she filed documentation regarding her medical expenses and updated physical therapy ("PT") records. Exhibits 22-23, ECF No. 11.

Following the initial status conference held on January 23, 2020, Respondent filed a status report from Respondent's counsel indicating she believed all required medical records had been filed and had identified no factual issues which needed to be addressed while awaiting the Health & Human Services review. ECF No. 17. On multiple occasions during the subsequent ten-month period, Petitioner filed updated medical records and periodic updates on the status of her demand. Exhibits 24-30, ECF Nos. 15, 15, 20, 26, 31-32, 37; e.g., Status Report, filed July 31, 2020, ECF No. 28 (regarding Petitioner's demand).

On December 8, 2020, Respondent filed a status report requesting clarification and additional documentation regarding the site of vaccination. ECF No. 38. In one typed entry in the vaccine record, the site of vaccination is listed as Petitioner's left, rather than right, deltoid. Exhibit 2 at 3. Other entries designated for information such as the site of vaccination are blank. Exhibit 2 at 2.

During the subsequent four-month period, Petitioner filed multiple status reports regarding her efforts to obtain additional documentation regarding the site of vaccination and to finalize her demand. ECF Nos. 39-40, 42. On April 22, 2021, Petitioner filed a status report providing answers to some of the questions and concerns raised in Respondent's December 8, 2020 status report, specifically those reiterated by court personnel in email correspondence with the parties. ECF No. 44; see Informal Remark, dated Apr. 5, 2021.

I have determined that a factual ruling regarding the site of vaccination is required in this case, and will assist in its ultimate disposition.

II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in her injured right deltoid, rather than her left deltoid as one typed entry in the vaccine documentation indicates.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the finding regarding site of vaccination after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I base the findings on the following evidence:

- The vaccine record initially filed by Petitioner consists of the following:
 - a Customer Statement Report providing the date, identifying information, and payment for the flu vaccine administered on September 9, 2017;
 - o the Vaccine Consent and Assessment signed by Petitioner;
 - a page containing two lines of typed information indicating the injection was administered intramuscularly in the left deltoid and that the lot number and expiration date are not available;

 an email, dated November 17, 2017, from an individual working at Petitioner's counsel's law firm to Petitioner inquiring about the left deltoid designation in the vaccine record which did not match the reports of a right arm injury in Petitioner's medical records and Petitioner's response confirming the vaccine was administered in her right deltoid.

Exhibit 2. The sections of the vaccine consent form designated for more detailed information such as lot number, expiration date, and site of vaccination are all blank. *Id.* at 2.

- On September 16, 2017, seven days after vaccination, Petitioner visited the emergency room ("ER"), "complaining of *right* arm pain since having a flu shot a week^[3] ago." Exhibit 3 at 9 (emphasis added). Upon examination, Petitioner "exhibit[ed] tenderness (at the deltoid and slight[ly] down the anterior bicep) and pain. *Id.* at 11 (emphasis in original omitted).
- On October 1, 2017, Petitioner sought treatment for right shoulder pain following a flu vaccine, identified as administered 30 days ago, from the Greenwood Health Center at the University of Utah. Exhibit 4 at 1385-86. Petitioner reported immediate swelling and redness, followed by pain and bruising. *Id.* at 1385. She exhibited no redness or swelling but limited range of motion ("ROM"), decreased strength, and numbness and tingling radiating down her arm, into her fingers. *Id.* at 1386.
- A few days later, on October 6, 2017, Petitioner sought treatment at Intermountain Healthcare - Cottonwood Family Practice for "right deltoid pain after a flu shot." Exhibit 6 at 7. While later entries, such as the physical therapy referral, list tendonitis in Petitioner's <u>left</u> deltoid (*id.* at 7, 12-13), entries related to the history provided by Petitioner and chief complaint for the visit in which the injury is attributed to the flu vaccine Petitioner received refer to the <u>right</u> shoulder (*id.* at 7, 9).
- When seen for her initial PT evaluation, on October 27, 2017, the reason for the PT is listed as constant pain in Petitioner's right arm since receiving

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³ One entry later in the ER medical records indicates the vaccination was administered two weeks ago. Exhibit 3 at 12. However, this one entry was from a registered nurse who examined Petitioner approximately 30 minutes after the initial intake. *Id.* Given the multiple entries provided by Petitioner during intake and at least one entry from the same registered nurse indicating the vaccination was one week ago, this entry appears to be incorrect, likely due to a simple mistake. *Id.* at 9, 11, 12.

the flu shot on September 19,⁴ 2017. Exhibit 7 at 1. Other entries also refer to the vaccination and injury as occurring in Petitioner's right arm and contain the same consistent descriptions of initial swelling and then radiating pain. *Id.* at 1, 2, 6.

- The medical record from Petitioner's next visit to Cottonwood Family Practice, on November 17, 2017, contains multiple entries referring to left should pain or simply shoulder pain. Exhibit 6 at 13-18. In this medical record, references to left arm pain are more prevalent than references to right arm pain. However, there are no entries regarding the flu vaccine Petitioner's believes is the cause of her injury, and the medical record contains one entry in which descriptions of both left and right arm pain are used within the same sentence. Id. at 14.
- In her affidavit, Petitioner alleges she received the flu vaccine in her right shoulder. Exhibit 1 at ¶ 4.
- In an April 22, 2021 status report, Petitioner indicated that she first requested her vaccine records from Kroger Pharmacy on October 4, 2017. Status Report at 1, ECF No. 44. On October 13, 2017, she received the documentation filed, along with the October 17, 2017 email correspondence. *Id.* at 1-2. Following subsequent requests to Kroger Pharmacy on July 18, 2019 and February 20, 2021, Petitioner received the same documentation. *Id.* at 2. Petitioner reported that the consent form, which lacks any site designation, was provided by her when requesting vaccination. She theorized that the notation regarding administration in Petitioner's left deltoid is from Kroger Pharmacy's computer system and the source of this information is from manual entry following vaccination by pharmacy personnel. *Id.* However, she acknowledged she "has been unable to verify this is the case as Kroger Pharmacy has been unwilling to confirm this information." *Id.* at 2-3.

The above medical entries show Petitioner consistently reported right shoulder pain which she attributed to her September 2017 vaccination. She provided this history to ER personnel, seen within six days of vaccination, to medical personnel at Greenwood Health Center and Cottonwood Family Practice within one month of vaccination, and to her physical therapist less than two months after vaccination. While originating from Petitioner, these statements are set forth in contemporaneous record, and should

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⁴ Due, most likely, to human error, this date is listed as September 19, 2017, rather than the correct date of September 9, 2017.

therefore be afforded greater weight than any current assertion or witness statement. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied <u>to</u> or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this class of information, even when the record in question simply memorializes what the petitioner said at the time.

Additionally, these medical records contain information regarding examinations and observations of Petitioner's right arm/shoulder condition and symptoms. Except for the medical records from Cottonwood Family Practice, which have been shown to be unreliable, all medical records describe a right shoulder injury.

The only evidence supporting a finding that the vaccination was administered in the left (opposite) arm is the typed, two line entry from the administration record provided by Kroger Pharmacy. That document includes a statement that the lot number and expiration date of the vaccine is unavailable. Exhibit 2 at 3. While the exact origin of this entry is unclear, it was most likely generated from information found in Kroger Pharmacy's computer system.

Based upon my experience resolving SPU SIRVA cases (approximately 650 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled in chambers, I find it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect. Many of these systems use a dropdown menu which may not be updated each time a separate vaccine is administered to a different individual. See, e.g., Desai v. Sec'y of Health & Human Servs., No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Human Servs., No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Human Servs., No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply because they come first – and in fact the nature of their creation provides some basis for not accepting them at face value.

⁵ Indeed, in a recent ruling by one of my special master colleagues, the pharmacist who had administered the relevant vaccination testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, because most vaccinees are right-handed. Because this ruling was issued on April 19, 2021, the period of any redaction request has not expired, and the ruling has not yet been posted to the court's website. However, the case number is 18-1977V, the pharmacist's testimony was deemed credible, and the ruling should be available to the public by May 2021.

More reliable is vaccine documentation which requires specific action on the part of the vaccine administrator to identify the site of vaccination which is performed close in time to the vaccination. See, e.g., Marion v. Sec'y of Health & Human Servs., No. 19-0495V, 2020 WL 7054414, at *8 (Fed. Cl. Spec. Mstr. Oct. 27, 2020). In this case, however, the consent form which would usually contain this designation is blank. Exhibit 2 at 2.

Accordingly, there is a dearth of evidence to support the determination that the vaccine was administered in Petitioner's left arm – while sufficient other reliable evidence supports the contrary finding. I thus determine, based on the record as a whole, that preponderant evidence establishes that the flu vaccine Petitioner received was most likely administered in her right deltoid on September 9, 2017.

V. Scheduling Order

During email correspondence regarding the next step in this case, Respondent's counsel represented that Respondent was interested in engaging in settlement discussions if I determined there was sufficient evidence to support Petitioner's claim regarding the site of vaccination in this case. See Informal Remark, dated Apr. 5, 2021. In her most recent status report regarding her demand, filed on March 23, 2021, Petitioner estimated she could forward her finalized demand and supporting documentation to respondent within 45 days, by May 15, 2021. ECF No. 42.

Petitioner shall file a status report updating me on the parties' settlement discussions by no later than <u>Tuesday</u>, <u>June 01</u>, <u>2021</u>. The status report shall indicate the date by which Petitioner provided, or intends to provide, a settlement demand and supporting documentation to Respondent. Additionally, Petitioner shall confirm whether any Medicaid lien exists, and if so, indicate the date by which Petitioner anticipates providing Respondent a letter from the appropriate state agency verifying the amount of the lien.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master